REMARKS

Claims 9-12, 16-18, 20-22, 24-26, 28-32, and 34-35 are pending in the application, with claim 9 being currently amended and claims 13-15, 19, 23, 27, and 33 being newly cancelled.

Claim 9, which is the only independent claim, has been amended by generally incorporating therein the subject matter of now cancelled claim 13 to more clearly define over the art of record. In particular, claim 9 now recites a process for producing lactoperoxidase comprising, in part, a step (4) for concentrating said leaching solution through an ultrafiltration membrane so that a protein content in said concentrated leaching solution becomes 0.9 to 15% to thereby effect precipitation of impurities in the concentrated leaching solution. Emphasis added. That is, ultrafiltration step (4) is conducted for separating lactoperoxidase from other proteins and, more specifically, the ultrafiltration step used for collecting lactoperoxidase generates an insoluble fraction (other proteins) and a soluble fraction, which is lactoperoxidase, within a concentrated fraction generated by ultrafiltration.

35 U.S.C. §102 rejections

Previously pending claims 9, 11, 13, 15-16, 18-20, 22-24, 26-30, and 32-35 stand rejected under 35 U.S.C. 102(b) as being unpatentable over Uchida U.S. Patent No. 5,516,675 ("the '675 patent"). In rejecting these claims, Examiner appears to fail to address the claimed subject matter of previously pending dependent claim 13, which is now incorporated in independent claim 9. Official Action at Pages 3 and 4. Indeed, while the '675 patent appears to disclose an ultrafiltration method, which is conducted for concentration and demineralization of

lactoperoxidase or the like which is a target product (Col. 6, lines 12 to 18), it does not at all discuss an ultrafiltration method for dividing lactoperoxidase as a soluble fraction and impurities as an insoluble fraction (precipitation). In other words, the '675 patent does not teach concentrating a leaching solution through an ultrafiltration membrane so that a protein content in the concentrated leaching solution becomes 0.9 to 15% to thereby effect precipitation of impurities in the concentrated leaching solution, as is now required by claim 9. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."). Accordingly, the process for producing lactoperoxidase in independent claim 9 is not anticipated by the '675 patent. Thus, the §102 rejection of claim 9, and its dependent claims, is overcome and must be withdrawn.

35 U.S.C. §103 rejections

Claims 9-35 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Uchida U.S. Patent No. 5,596,082 ("the '082 patent"), Burling U.S. Patent No. 5,149,647 ("Burling"), Kussendrager U.S. Patent No. 6,010,698 ("Kussendrager"), Souppe FR 2841747 as evidenced by U.S. Patent No. 7,247,331 ("Souppe"), and Lihme U.S. Patent No. 5,780,593 ("Lihme"). Applicants respectfully disagree.

Even assuming *arguendo* that one skilled in the art would combine Uchida, Burling, Kussendrager, Souppe, and Lihme, which we assert one would not, the combination still fails to make obvious Applicant's process for producing lactoperoxidase as now recited in claim 9. Indeed, to establish *prima facie* obviousness of a claimed invention, it is certainly well

established that all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974); *See also* MPEP §2143.03 (citing *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970))(To establish *prima facie* obviousness of a claimed invention, it is certainly well established that "all words in a claim must be considered when judging the patentability of that claim against the prior art or suggested by the prior art." (emphasis added)). In the instant case, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness for the reasons that follow.

Again, independent claim 9 specifically requires a step (4) for concentrating said leaching solution through an ultrafiltration membrane so that a protein content in said concentrated leaching solution becomes 0.9 to 15% to thereby effect precipitation of impurities in the concentrated leaching solution.

Upon review of the '082 patent, this reference discloses in Example 5 that an ultrafiltration film is used for demineralization, and lactoperoxidase can be formed such that a cation exchanger is used to adsorb milk materials, and then, after the cation exchanger is washed, elution of lactoperoxidase is conducted with a sodium chloride aqueous solution. However, there is no disclosure at all in the '082 patent that an ultrafiltration method is used for dividing lactoperoxidase as a soluble fraction and impurities as an insoluble fraction (precipitation). In other words, the '082 patent simply fails to disclose a step for concentrating a leaching solution through an ultrafiltration membrane so that a protein content in the concentrated leaching solution becomes 0.9 to 15% to thereby effect precipitation of impurities in the concentrated leaching solution, as is required by claim 9. In that regard, the additional art, i.e., Burling,

Kussendrager, Souppe, and Lihme, cited by Examiner is submitted not to change this situation.

Specifically, upon review of Burling, Burling discloses a microfiltration (MF) to prevent clogging of an ion exchanger, wherein the clogging of an ion exchanger is caused by occurrence of particles of globular fat and protein aggregate in milk materials when cation exchange treatment is conducted at a high rate. Col. 3, lines 44 to 47. Also, the microfiltration is adopted in Burling as a pretreatment for the cation ion exchange treatment. Col. 3, lines 47 to 51. However, the order of production steps in Burling is different from those of the present invention wherein a leaching solution is concentrated with an ultrafiltration membrane after cation exchange treatment is conducted. Furthermore, there is no disclosure at all in Burling that an ultrafiltration method is used for dividing lactoperoxidase as a soluble fraction and impurities as an insoluble fraction (precipitation). In other words, Burling, like the '082 patent, simply fails to disclose a step for concentrating a leaching solution through an ultrafiltration membrane so that a protein content in the concentrated leaching solution becomes 0.9 to 15% to thereby effect precipitation of impurities in the concentrated leaching solution, as is required by claim 9.

Upon review of Kussendrager, Kussendrager discloses a method wherein milk or milk derivative is passed through a cation exchange resin of a cation exchanger to adsorb lactoperoxidase and lactoferrin to the resin, and furthermore, salt solutions of different concentrations are passed through the cation exchanger to obtain a lactoferrin-containing fraction and a lactoperoxidase-containing fraction. Col. 1, lines 15 to 25. Subsequently, treatments of desalting, concentration, removing bacteria and drying are conducted for the lactoferrin-containing fraction and the lactoperoxidase-containing fraction to isolate lactoperoxidase and

lactoferrin. However, there is no disclosure at all in Kussendrager that an ultrafiltration method is used for dividing lactoperoxidase as a soluble fraction and impurities as an insoluble fraction (precipitation). In other words, Kussendrager, like the '082 patent and Burling, simply fails to disclose a step for concentrating a leaching solution through an ultrafiltration membrane so that a protein content in the concentrated leaching solution becomes 0.9 to 15% to thereby effect precipitation of impurities in the concentrated leaching solution, as is required by claim 9.

Upon review of Souppe, Souppe discloses a method wherein milk materials are adsorbed by a cation exchange resin, then the adsorbed milk materials are eluted with a salt solution, and desalting is carried out by an ultrafiltration method. Col. 2, lines 44 to 54. However, there is no disclosure at all in Souppe that an ultrafiltration method is used for dividing lactoperoxidase as a soluble fraction and impurities as an insoluble fraction (precipitation). In other words, Souppe, like the '082 patent, Burling, and Kussendrager, simply fails to disclose a step for concentrating a leaching solution through an ultrafiltration membrane so that a protein content in the concentrated leaching solution becomes 0.9 to 15% to thereby effect precipitation of impurities in the concentrated leaching solution, as is required by claim 9.

Finally, upon review of Lihme, Lihme discloses an ultrafiltration method which is conducted for concentration, desalting and the like. Col. 6, lines 12 to 18. However, there is disclosure in Lihme that an ultrafiltration method is used for dividing lactoperoxidase as a soluble fraction and impurities as an insoluble fraction (precipitation). In other words, Lihme, like the '082 patent, Burling, Kussendrager, and Souppe, simply fails to disclose a step for concentrating a leaching solution through an ultrafiltration membrane so that a protein content in

the concentrated leaching solution becomes 0.9 to 15% to thereby effect precipitation of impurities in the concentrated leaching solution, as is required by claim 9.

In view of the above, when combined, the '082 patent, Burling, Kussendrager, Souppe, and Lihme fail to provide all of the elements of Applicants' claimed process for producing lactoperoxidase. That is, Examiner has not established a *prima facie* case of obviousness based on these disclosures insofar as these references, collectively, fail to disclose a step for concentrating a leaching solution through an ultrafiltration membrane so that a protein content in the concentrated leaching solution becomes 0.9 to 15% to thereby effect precipitation of impurities in the concentrated leaching solution.

Further, as is apparent from the results of Test Example 2 of the present specification, the present invention has unexpected results with excellent effects, wherein even if purified water or the like is added to the concentrated fraction obtained by the ultrafiltration treatment, and subsequent concentration is further conducted again, the precipitation is no longer dissolved in the purified water or the like. That is, the present invention can have synergistic effects wherein both treatments of removing impurities and treatments of demineralization and concentration can be conducted simultaneously. Accordingly, it would not be within the purview of a skilled artisan to expect the specific and excellent effects of the present invention from the cited references.

For all of the above reasons, the rejections are overcome and must be withdrawn. Applicants, thus, respectfully submit that independent claim 9, along with its dependent claims, is allowable over the cited references.

Conclusion

As a result of the remarks given herein, Applicants submit that the rejection of the pending claims has been overcome. Therefore, Applicants respectfully submit that this case is in condition for allowance and request allowance of the pending claims.

If Examiner believes any detailed language of the claims requires further discussion, Examiner is respectfully asked to telephone the undersigned attorney so that the matter may be promptly resolved. Applicants also have submitted all fees believed to be necessary herewith. Should any additional fees or surcharges be deemed necessary, Examiner has authorization to charge fees or credit any overpayment to Deposit Account No. 23-3000.

Respectfully submitted,
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